



Press release

## **Ipsen's partner Roche announces amendment of the trial protocols for the taspoglutide phase III programme**

**Paris (France), 18 June 2010** - Ipsen (Euronext: IPN – ADR: IPSEY), a global biopharmaceutical group, today announced that its partner Roche today announced the implementation of a risk mitigation plan in the taspoglutide Phase III programme. Taspoglutide, the first once weekly glucagon-like peptide-1 (GLP-1) analogue based on a human sequence, originating from Ipsen's research is developed by Roche. This compound is similar to the natural hormone GLP-1 which has a key role in blood sugar regulation.

In the Phase III studies, the incidence of hypersensitivity reactions reported as related to taspoglutide is higher than expected for the study population, although it remains uncommon (i.e. incidence < 1%). The most frequently reported symptoms in patients who developed hypersensitivity reactions were skin reactions and gastrointestinal symptoms, while cardiovascular and respiratory symptoms were less frequent. All patients recovered without complications.

Roche has identified a potential association between hypersensitivity reactions and anti-drug antibodies (ADAs). In consultation with the Food and Drug Administration (FDA), Roche has decided to implement a risk mitigation plan, which has been communicated to Health Authorities globally. The plan is designed to identify patients at potential risk of these reactions. As such, ADA levels will be routinely monitored and patients that develop pre-specified ADA levels will discontinue treatment and continue to be monitored in the trials. The continued safety of patients in the clinical development programmes remains the highest priority for Roche. Roche is committed to working with Health Authorities globally to continue the development of taspoglutide to meet the needs of patients with type 2 diabetes. Roche is investigating the cause of the hypersensitivity reactions and testing specific means to resolve this issue. The impact of this plan on the project and in particular on the timelines for regulatory filing are currently being assessed, however, a minimum of 12 to 18 months delay is anticipated.

Roche looks forward to sharing with the medical community at the forthcoming American Diabetes Association, data from five phase III trials demonstrating that taspoglutide delivered combined benefits of consistent robust glycemic control, across a wide spectrum of patients versus exenatide, sitagliptin and even the highest dose of insulin glargine used in a development program. In addition, taspoglutide was associated with a low risk of hypoglycaemia and clinically important weight loss. Over the next few weeks, Roche also expects to get the headline data on the 52-week extended trials.

### **About the T-emerge Programme**

The T-emerge Phase III clinical trial programme is designed as multicenter, multi-country, randomized, controlled (active or placebo), double-blind and open studies. Over 6,000 patients have been enrolled in the eight studies that comprise the T-emerge programme. Studies include two parallel taspoglutide arms including 10 mg once weekly and 10 mg once weekly titrated up to 20 mg once weekly after four weeks. Four of the eight studies have active comparators, including exenatide, sitagliptin, insulin glargine and pioglitazone.



### **About Taspoglutide (R1583)**

Taspoglutide was selected from a family of human once-weekly long-acting glucagon-like peptide-1 (GLP-1) analogues with structural modifications which confer intrinsic controlled release properties. Ipsen is the originator of the concept of matrix free sustained release formulation applied to therapeutic peptides and proteins. Taspoglutide is being developed, by Roche, as a novel and innovative treatment for patients with type 2 diabetes mellitus, the fourth leading cause of death in most developed countries. The structure of the molecule is similar to that of the natural human hormone GLP-1, and has the potential for intervals of up to two weeks in between administration without the use of a matrix.

### **About the agreement**

Roche exercised its licensing option for taspoglutide from Ipsen in 2006 and acquired exclusive worldwide rights to develop and market taspoglutide, except in Japan where these rights are shared with Teijin and in France where Ipsen has elected to retain co-marketing rights.

### **About Ipsen**

Ipsen is a global biopharmaceutical group with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, which significantly contribute to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. Nearly 900 people are dedicated to the discovery and development of innovative drugs for patient care. Nearly 900 people are dedicated to the discovery and development of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. Ipsen's shares are traded on Segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Service de Règlement Différé" ("SRD") and the Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit our website at [www.ipсен.com](http://www.ipсен.com).

### **Ipsen's Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents



filed with the French Autorité des Marchés Financiers.

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